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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,653	04/15/2004	David D. Barone	P1830 US	2140

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
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EXAMINER
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MCEVOY, THOMAS M

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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09/02/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,653	<b>Applicant(s)</b> BARONE, DAVID D.	
	<b>Examiner</b> THOMAS MCEVOY	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 6<sup>th</sup>, 2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 4-10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,375,670 B1) in view of Gilson et al. (US 6,336,934 B1) and in further view of Ouriel et al. (US 2003/0097094).

Greenhalgh discloses a tubular intraluminal filter, as best seen in Figure 1, comprising: proximal and distal ends (40 and 38), a longitudinal axis (18), a collapsed configuration and an expanded configuration (Figures 2a and 2b); the expanded configuration having a generally cylindrical body and adjoining proximal and distal sections that taper from the cylindrical body to proximal and distal filter ends, respectively (Figure 2b: when expanded against a vessel wall, as is the intended expandable state, the filter body portion is generally cylindrical); wherein relative movement of the proximal and distal ends along the axis accompanies transformation of the filter between the collapsed configuration and the expanded configuration (coaxial movement of the filter ends accompanies expansion and contraction in Figures 2a and 2b; opposite axial movement in combination with coaxial movement accompanies expansion and contraction in the Figure 5 embodiment); the filter comprising: a first array of braided filaments extending proximally from the filter distal end to a proximal terminus within a junction region between the cylindrical body and the tapered proximal section (30); and a second array of filaments extending proximally from the filter distal end to the filter proximal end, the filaments in the second array being inter-braided with the first array to define the filter distal section with a sufficiently dense braid to filter

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embolic debris (Figure 8, second box from top); the filter proximal section being defined by two or more strands (32); each strand being intra-braided solely from a plurality of filaments of the second array, none of the strands being braided with any other strand whereby the space between adjacent strands defines an unobstructed filter inlet port (42); wherein the proximal terminus of the first array is coupled to the second array by a retention member comprising joints formed where filaments of the first array overlap filaments of the second array wherein the joints are formed by one or more joining methods selected from adhesive bonding, heat bonding, melt bonding, soldering, brazing, welding, laser welding, resistance welding, and spot welding (column 6, lines 43-45); wherein the filter has a shape memory of the expanded configuration and has a shape memory of the collapsed configuration (see Abstract); a filter catheter comprising a flexible elongate shaft and a filter as described above mounted about a distal end of the shaft (20), and an actuation system for causing relative movement of the filter proximal and distal ends along the longitudinal axis of the filter which is connected to a flexible elongate shaft (figures 2a and 2b). Regarding claim 5, the retention member can be interpreted as comprising filaments themselves as in claim 6. Therefore, since Greenhalgh discloses that the filaments can be woven into a sleeve (col. 5, lines 29-31) and is elastically deformable (Abstract), the limitations of claim 5 are met. Greenhalgh does not disclose that the filaments of the second array are braided to form two or more strands in the filter proximal section. Attention is drawn to Gilson et al. who disclose a filter of similar structure to Greenhalgh as well as the claimed invention, as best seen in Figure 39, where the strands of the proximal section are bundled together into four

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strands which creates four large inlet openings in the proximal section (column 6 - lines 45 to 47; Brief Description of Drawings). Further attention is drawn to Ouriel et al. who teach that the strands of the proximal section may be bundled by intra-braiding 40 wires into 10-wire bundles, where the intra-braided bundles (or strands) extend the full length of the proximal section (paragraph 0067; Figure 13). It would be obvious to one of ordinary skill in the art, having the teachings of Greenhalgh, Gilson et al. and Ouriel et al. before him or her to intra-braid the filaments of the second array, in the proximal section, to form two to four strands where the intra-braided strands extend the full length of the proximal section, in order to create the larger inlet holes of the proximal section as disclosed by Gilson et al. and Ouriel et al.

5. In an alternative interpretation, claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,375,670 B1), Gilson et al. (US 6,336,934 B1) and Ouriel et al. (US 2003/0097094) as applied to claim 4 above, and further in view of Hyodoh et al. (US 2003/0040771).

The combination of Greenhalgh, Gilson et al. and Ouriel et al. discloses the invention discussed above but fails to disclose a retention member comprising an elastic encapsulating sleeve where the sleeve is interpreted to be a separate structure from the braided filaments. Hyodoh et al. disclose an intra-luminal device which can partially restrict blood flow (making it a filter; paragraph 0227), as best seen in Figure 34. The device is of similar structure as described above and nearly identical to the 'filters' disclosed by Hyodoh et al. (Figures 6-9 and 51) but further includes an expandable (or elastic) encapsulating sleeve (710) which is joined to the filaments

(paragraph 0230) to cover (or retain within) the body of the filter (as seen in Figure 34) in order to facilitate manipulation of the filter within a sheath (paragraph 0230). Hyodoh et al. disclose that the sleeve need only cover a portion of the braided device. The jacket allows for easier manipulation and delivery of their braided device from a sheath. It would have been obvious to one having ordinary skill in the art and having the teachings of Greenhalgh, Gilson et al., Ouriel et al. and Hyodoh et al. before him or her to cover a portion of the filter with an expandable sleeve, in order to facilitate manipulation of the filter within a delivery sheath, where it would be obvious to cover any portion of the filter which could be more easily manipulated within the sheath by enclosure within a sleeve, while not substantially obstructing the inlet holes in the proximal section. This reasonably would include the junction between the proximal and distal arrays since this area represents the middle and most expansive portion of the filter which would be in more contact with a delivery sheath than the ends as shown in Figure 2A of Greenhalgh. Furthermore, the coupling of the filaments between the arrays would be facilitated by the fixed attachment of the sleeve to the filaments of both arrays at the junction region.

6. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,375,670 B1), Gilson et al. (US 6,336,934 B1), Ouriel et al. (US 2003/0097094) and further in view of Molgaard-Nielsen et al. (US 4,619,246).

Greenhalgh discloses a method for making the filter comprising: braiding multiple filaments to form a filter precursor tube (Figure 8, top two boxes); demarcating tube regions that are intended to become a proximal filter section, a cylindrical filter body,

and a junction region there between; severing selected filaments at the junction and removing severed filaments from the proximal filter section (Figure 8, third and forth box from top; gathering the ends of a filter tube and removal of filaments from a proximal end implies a determination or demarcation of tube regions intended to become the proximal, cylindrical and junction regions as claimed). Greenhalgh does not disclose dividing the un-severed filaments in the proximal filter section into two or more groups; intra-braiding each group of filaments into a corresponding strand; and heat-treating the filter to set a selected shape thereof. Gilson et al. disclose a filter of similar structure to Greenhalgh as well as the claimed invention, as best seen in Figure 39, where the strands of the proximal section are bundled together into two or more strands (column 6 - lines 45 to 47; Brief Description of Drawings). Ouriel et al. teach that the strands of the proximal section may be bundled by intra-braiding 40 wires into 10-wire bundles and where the intra-braided bundles (or strands) extend the full length of the proximal section (paragraph 0067; Figure 13). Gilson et al. further disclose that the filter material could have shape memory to the expanded state (column 6, line 33) where heat treatment is a known technique in the art for obtaining shape memory characteristics for intraluminal filters as taught by Molgaard-Nielsen et al. (column 1, paragraph 3). It would be obvious to one of ordinary skill in the art, having the teachings of Greenhalgh, Gilson et al., Ouriel et al. and Molgaard-Nielsen et al. before him or her, to bundle the filaments of the proximal section to form two or more strands as taught by Gilson et al. (to create larger inlet pores), where the strands can be bundled by intra-braiding and



extend the full length of the filter proximal section as taught by Ouriel et al., and further heat treat the filter as taught by Molgaard-Nielsen et al. (to set a desired shape).

### ***Response to Arguments***

7. Applicant's arguments filed May 6<sup>th</sup> 2008 have been fully considered but they are not persuasive. Applicant argues that Gilson only discloses connecting bundles of filaments to a single individual fibers. Examiner asserts that this is only one interpretation and not the most probable. Gilson clearly shows multiple filaments at the proximal end of the filter. It would certainly seem that these are the result of unbundling the strands, labeled 'D' by applicant. Even if one takes the interpretation that strands D are individual fibers, Gilson et al. still disclose reducing the number of filaments in the distal section to a lower number in the proximal section. Ouriel et al. at least teach that this reduction can be made by intra-braiding so the combination is proper and not based on hindsight reasoning. Applicant argues that the filaments of Greenhalgh are not part of the filter but only serve to support a separate filter. Examiner brings attention to Figure 8 of Greenhalgh where it is clearly stated that the filaments and yarns are inter-braided to form a surface having a predetermined porosity; i.e., inter-braided into a filter. Applicant argues that Gilson et al. do not show two arrays of filaments. Examiner has only used Figure 39 of Gilson et al. to demonstrate that bundling of filaments from a braided distal filter section to form individual strands of a proximal section is disclosed in the prior art. This feature is combined with Greenhalgh who discloses a filter made of 2 arrays of inter-braided filter members where one array is used to make the strands of the proximal section. Applicant argues that Hyodoh et al. disclose that their jacket is

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only usable with an occluder and that it would not permit proper functioning of a filter.

Examiner had further explained in this Office Action that Hyodoh et al. disclose filters of nearly identical construction in the same reference and Hyodoh et al. disclose that their jacket need only cover a portion of the occluding device, where the occluding device can allow blood to flow through and therefore act as a filter. The combination of these disclosed elements, in Examiners view, has made combining the jacket with other filters obvious. If the jacket of Hyodoh et al. allows for easier delivery of their braided occluders which have a very similar design as their braided filters then it should also allow for easier delivery of other prior art braided filters. Applicant continues to make the argument that the level of skill was not resolved or articulated in the applied prior art. Examiner respectfully disagrees with this assertion and points out that the level of skill that was applied in the prior art of reference was (and is again) articulated as “one of ordinary skill in the art”. Applicant requests further explanation of the term: a person of ordinary skill. Examiner asserts that there are many interpretations of this term. One interpretation that would apply to the rejections set forth in this action is: a hypothetical person who is presumed to have known the relevant art at the time of the invention (MPEP 2141); able to fit the teachings of multiple patents together like pieces of a puzzle (KSR, 82 USPQ2d at 1397; MPEP 2141).

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F 8:30 - 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TM

***/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731***